Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Universal Health Care – King
Docket No. A-11-38
Decision No. 2383
June 3, 2011

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Universal Health Care – King (Universal), a North Carolina skilled nursing facility (SNF) that participates in the Medicare program, requests review of the November 5, 2010 decision of Administrative Law Judge Steven T. Kessel, *Universal Health Care – King*,, DAB CR2278 (2010) (ALJ Decision). The ALJ sustained CMS's determination that Universal failed to comply substantially with the participation requirements at 42 C.F.R. §§ 483.25(l) and 483.75(j)(1). The ALJ upheld CMS's imposition of civil money penalties (CMPs) against Universal in the amounts of $3,050 per day for the period March 21, 2009 through September 27, 2009, and $150 per day for the period September 28, 2009 through November 2, 2009.

For the reasons discussed below, we affirm the ALJ Decision.

Legal Background

To participate in Medicare, a SNF must comply with the requirements for long term care facilities set forth in 42 C.F.R. Part 483, subpart B. 42 C.F.R. § 483.1. State agencies under contract with CMS perform surveys to assess compliance with the requirements. 42 C.F.R. §§ 488.300, 488.305. Deficiencies – failures to meet participation requirements – are reported by the state agency on a standard form called a "Statement of Deficiencies" (SOD). 42 C.F.R. § 488.301; State Operations Manual (SOM), Appendix P (accessible at http://cms.gov/manuals/Downloads/som107ap_p_ltcf.pdf). The SOD identifies each deficiency under the applicable requirement, citing both the regulation at issue and the corresponding "tag" number used by surveyors for organizational purposes.

The introductory language of section 483.25 of the regulations, titled "Quality of care," provides that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." Subsection 483.25(l), titled "Unnecessary drugs," provides that "[e]ach resident's drug regimen must be free from unnecessary drugs." The regulation defines

"unnecessary drug" to mean any drug used in "excessive dose (including duplicate drug therapy);" or "[f]or excessive duration;" or "[w] ithout adequate monitoring;" or "[w]ithout adequate indications for its use;" or [i]n the presence of adverse consequences which indicate the dose should be reduced or discontinued;" or "[a]ny combinations of" the listed reasons.

Section 483.75 sets forth the requirements for the "[a]dministration" of long term care facilities. Section 483.75(j) addresses "[l]aboratory services." Subsection 483.75(j)(1) provides that a "facility must provide or obtain laboratory services to meet the needs of its residents" and that the "facility is responsible for the quality and timeliness of the services." Subsection 483.75(j)(2) provides that the "facility must . . . [p]rovide or obtain laboratory services only when ordered by the attending physician" and "[p]romptly notify the attending physician of the findings . . . ."

CMS may impose enforcement remedies (including CMPs) when it determines on the basis of survey findings that a facility is not in "substantial compliance" with one or more participation requirements. 42 C.F.R. § 488.402. "Substantial compliance means a level of compliance . . . such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. Under the regulations, the term "noncompliance" refers to "any deficiency that causes a facility to not be in substantial compliance." *Id.*

CMS determines the amount of a CMP based in part on the "seriousness" (scope and severity) of the facility's noncompliance. 42 C.F.R. § 488.404(a). The most serious deficiencies are those that place residents in "immediate jeopardy." 42 C.F.R. § 488.404(b). Immediate jeopardy is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. The minimum per-day amount for a CMP in the case of immediate jeopardy is $3,050. 42 C.F.R. § 488.438(a)(1). A per-day CMP of $50 to $3,000 may be imposed for noncompliance at less than the immediate jeopardy level. *Id.*

Case Background[1]

A. The surveys and CMS determinations

The North Carolina Department of Health and Human Services, Division of Health Service Regulation (State agency), conducted a complaint investigation survey of Universal that ended on September 26, 2009. The State agency concluded that Universal

[1] The information in this section is drawn from undisputed findings in the ALJ Decision and the record before the ALJ. It is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings or conclusions.

was not in substantial compliance with the participation requirements at 42 C.F.R. §§ 483.20(d), 483.20(k)(1), 483.25(l) and 483.75(j)(1). CMS Ex. 1. On October 6, 2009, CMS issued a notice to Universal that, based on the survey findings, CMS had determined that conditions at Universal constituted immediate jeopardy to resident health and safety and substandard quality of care as of March 21, 2009. P. Ex. 29. CMS imposed a CMP on Universal in the amount of $3,050 per day beginning March 21, 2009, to continue until the jeopardy was removed or the facility was terminated. *Id.*

The State agency conducted a recertification and revisit survey of Universal that ended on October 15, 2009. P. Exs. 30-31. The survey found that the immediate jeopardy ended on September 28, 2009. *Id.* The survey further found, however, that Universal continued not to be in substantial compliance based on new deficiencies identified under sections 483.25, 483.25(f)(2), and 483.35(i). P. Ex. 31, at 4-12.

By letter dated November 2, 2009, CMS notified Universal that as a result of the October survey findings, the CMP would be $3,050 per day from March 21 through September 27, 2009, and $150 per day beginning September 28, 2009 and continuing until substantial compliance was achieved or the facility was terminated. P. Ex. 30. By letter dated December 14, 2009, CMS notified Universal that CMS determined that Universal returned to substantial compliance on November 3, 2009. CMS Ex. 9.

Universal timely requested an ALJ hearing to contest the September survey findings and related sanctions. Following the submission of pre-hearing briefs, exhibits, and proposed witnesses, the parties agreed to present the case for decision upon written submissions in lieu of an in-person hearing.

B. The ALJ Findings and Conclusions

The allegations of noncompliance addressed by the ALJ primarily involve the care provided to a resident identified in the September 2009 complaint survey as Resident 1 (R1). The ALJ described R1 as an "elderly" woman with "multiple medical problems." ALJ Decision at 4. In February 2007, R1 developed deep vein thromboses (blood clots) in her legs. On February 10, 2009, R1's physician ordered R1 to be administered Coumadin, described by the ALJ as "an extremely powerful anticoagulant drug," and Lovenox, another anticoagulant. *Id.* at 3-4. Coumadin, the ALJ found, "has a very narrow therapeutic range" and poses a risk of fatal, uncontrollable bleeding. *Id.* at 3. The ALJ also found that "[e]very individual responds uniquely" to Coumadin, and its "anticoagulant effects may vary from individual to individual" based on a multitude of factors. *Id.*

In order to measure whether the Coumadin was in a safe and therapeutic range, R1's physician ordered daily Prothrombin Time and International Normalized Ratio (PT/INR) testing for R1 on the same day that he first prescribed the anticoagulants, February 10,

2009. *Id.* at 4; CMS Ex. 7, at 2. The ALJ found, however, that Universal's staff failed to perform or obtain INR tests for R1 on February 11, 12, and 13, 2009. When an INR was obtained on February 14, 2009, the ALJ determined, "the results were critically high," and the physician ordered the Coumadin to be temporarily discontinued, until February 16. ALJ Decision at 4; CMS Ex. at 7, at 3. "On February 24, 2009, the ALJ stated, another physician-ordered INR test was obtained and showed a "dangerously high" reading. ALJ Decision at 4. The ALJ found "no evidence that the physician was notified of this reading." *Id.* However, the ALJ determined, on February 26, 2009, R1's physician "evidently" was notified of "another very high INR result" and "ordered for a second time that administration of Coumadin and Lovenox be discontinued." *Id.*

On February 28, 2009, R1's physician ordered that Coumadin be restarted at a reduced dose, and daily INR testing. ALJ Decision at 4; CMS Ex. 7, at 7. The physician later ordered the administration of another anticoagulant, Arixtra, because R1's INR readings were subtherapeutic. ALJ Decision at 4. After "a March 10 INR showed a dangerously high reading," the ALJ found, the physician discontinued the Arixtra. *Id.*

On March 3, 2009, the ALJ found, "for reasons that are not explained, [Universal's] staff failed to give the resident her prescribed daily dose of Coumadin," and on "March 2, 4, and 5, the resident's INR readings were subtherapeutic." *Id.* The ALJ determined that Universal did not notify the physician of these results until March 5, 2009. In addition, the ALJ found that Universal "failed to perform an INR test on March 14 despite the fact that the physician had ordered daily INR readings." *Id.* The ALJ also found that on March 16, 2009, R1's physician ordered an INR test to be performed on March 21, 2009. No INR test was performed on that date, however, and "staff continued to administer Coumadin to the resident through March 23, 2009." *Id.* at 4-5.

On March 24, 2009, the ALJ found, Universal's staff observed "bruising in the vicinity of [R1's] breast and armpit," and her physician "ordered that she be sent to the emergency room." *Id.* at 5. Emergency room personnel noted "severe swelling and bruising," and recorded R1's INR "at a dangerously high level." *Id.* The ALJ determined that R1 was "treated for a toxic reaction to Coumadin, but she died on March 25, 2009." *Id.* According to the ALJ, the "cause of the resident's death was given as Coumadin poisoning and internal bleeding." *Id.*

The ALJ determined that the evidence relating to Universal's care of R1 "overwhelmingly" supported the conclusion that Universal failed to comply substantially with the requirements at sections 483.25(l) and 483.75(j)(1) due to "multiple failures" to conduct physician-ordered INR tests, failures to report timely to the physician critically high and subtherapeutic test results, and the failure to address the resident's Coumadin therapy in her care plan. ALJ Decision at 3, 5. These failures, the ALJ determined, violated section 483.25(l) "because they enabled [R1] to receive excessive and potentially life-threatening doses of Coumadin." *Id.* at 3. The ALJ also determined that Universal

violated section 483.25(j)(1) because it failed to obtain physician-ordered laboratory tests to meet R1's medical needs. *Id.*

The ALJ further concluded that Universal did not prove to be clearly erroneous CMS's determination that the facility's noncompliance posed immediate jeopardy to resident health and safety. That Universal failed to obtain or perform five physician-ordered PT/INR tests for R1 and failed to detect these errors, the ALJ held, demonstrated a "systemic weakness in the way [Universal] monitored residents who received Coumadin." *Id.* at 6. These conditions, the ALJ concluded, "put residents at risk for serious injury, harm, impairment or death," whether or not the noncompliance directly caused R1's death. *Id.*

In addition, the ALJ found that Universal's noncompliance at the immediate jeopardy level "persisted from March 21 through September 27, 2009." *Id.* at 7. According to the ALJ, Universal instituted multiple corrective actions completed by April 7, 2009 that "focused on assuring that staff members and laboratory personnel performed those tests that are ordered by a resident's physician." *Id.* at 8. However, the ALJ determined, Universal's noncompliance involved more than the failure to obtain physician-ordered INR tests, and it was not until all of the problems were comprehensively addressed under its plan of correction that the immediate jeopardy was abated.

The ALJ additionally found that Universal did not challenge the "[t]hree [new] findings of substantial noncompliance [that] were made at the October Survey." *Id.* at 6. The ALJ concluded that these deficiencies, cited under 42 C.F.R. §§ 483.25, 483.25(f)(2) and 483.35(i), were therefore "administratively final," and CMS was authorized to impose remedies based on them. *Id.*

Finally, the ALJ determined that the CMPs imposed by CMS were reasonable.

Standard of Review

The Board's standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. The Board's standard of review on a disputed finding of fact is whether the ALJ decision is supported by substantial evidence on the record as a whole. *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs,* http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html; *Batavia Nursing and Convalescent Inn*, DAB No. 1911, at 7 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. App'x 664 (6th Cir. 2005).

Analysis

Universal contests the ALJ Decision on multiple grounds, which we address below. First we explain that in reaching the conclusion that Universal failed to comply substantially with sections 483.25(l) and 483.75(j)(1), the ALJ properly construed the regulations and that substantial evidence supports his determination. We then discuss why we conclude that the ALJ did not err in sustaining CMS's determination that Universal's noncompliance posed immediate jeopardy from March 21, 2009 through September 27, 2009. Finally, we explain that the ALJ properly upheld the amounts of the CMPs.

A. The ALJ's determination that Universal failed to comply substantially with 42 C.F.R. §§ 483.25(l) and 483.75(j)(1) is free of legal error and supported by substantial evidence.

Universal's arguments

Universal argues that the ALJ "cite[d] no legal authority for his finding of noncompliance with [the unnecessary drugs or laboratory services requirements] or for the underlying rationale." P. Br. at 8. Rather, Universal avers, the ALJ cited the SOD and the testimony of the Surveyor, who was only "a fact witness, as authority for this finding and conclusion." *Id*. (emphasis in original); *see also* P. Br. at 12. Universal also contends that the SOD contains "simply allegations" of noncompliance and cannot be used "to establish a *prima facie* case of noncompliance." P. Br. at 8. Furthermore, Universal argues that the ALJ erred in determining that it was noncompliant with section 483.25(j)(1) because that regulation "addresses services performed by the laboratory," not "a facility's alleged failure to draw a blood sample as ordered." P. Br. at 10-11, *citing Woodland Village Nursing Center*, DAB CR1668 (2007), *aff'd,* DAB No. 2172 (2008); P. Ex. 23, ¶ 3 (Declaration of William Simonson, PharmD).

In addition, Universal avers that the ALJ improperly cited its "alleged failure to properly care plan as a basis for finding [the facility] noncompliant with [sections 483.25(l) and 483.75(j)(1)]." P. Br. at 11. The SOD, Universal argues, cited the care planning deficiencies separately, under sections 483.20(d) and 483.20(k)(1), and at a level of severity less than immediate jeopardy. "Having cited the facility in this manner and at this level for the care planning issue," Universal avers, "CMS should not have been permitted to recast the care planning issue as a basis for the I[mmediate] J[eopardy] deficiencies." *Id*. Furthermore, Universal contends, there is "no regulatory requirement that a provider reflect every condition, medication or change in condition or treatment in a resident's care plan." *Id.* Absent a regulation specifically establishing that comprehensive care plans must address Coumadin therapy, Universal argues, CMS was required, but failed, to "establish via evidence or expert testimony the applicable standard of care upon which it base[d] [the] deficiency." *Id.* at 12. In any event, Universal contends, its staff provided all of the monitoring that R1 required.

The ALJ correctly construed the regulations and properly relied on the Surveyor's testimony addressing professional standards of quality care.

We reject Universal's contentions that the ALJ "cite[d] no legal authority" for his determination. P. Br. at 8. The legal authorities construed and applied by the ALJ (and shown on the SOD as corresponding to the survey deficiency findings) are the unnecessary drugs requirements at 42 C.F.R. § 483.25(l), and the facility administration requirements at 42 C.F.R. § 483.75(j)(1). The plain language of section 483.25(l) requires a SNF to ensure that resident drug regimens are "free from unnecessary drugs," which include "excessive dose[s]," drugs administered "[w]ithout adequate monitoring," and drugs administered when "adverse consequences . . . indicate the dose should be reduced or discontinued." The plain language of section 483.75(j)(1) requires a SNF to "provide or obtain laboratory services to meet the needs of its residents" and states that the "facility is responsible for the quality and timeliness of the services."

The ALJ correctly construed and applied section 483.25(l).

Evaluating whether Universal complied with the unnecessary drugs regulation in its care of R1, the ALJ cited Surveyor Jean Farley's testimony to support his factual findings of the "significant risks" posed by Coumadin, as well as the applicable professional standards of nursing care for residents taking the drug. ALJ Decision at 3, *citing* CMS Ex. 10 (Declaration of Surveyor Jean L. Farley, Registered Pharmacist). As noted, the ALJ found that Coumadin "poses significant risks," including "life-threatening uncontrollable bleeding," that every "individual responds uniquely to the drug," and that its "anticoagulant effects may vary . . . as a result of factors that include the individual's age, diet, health, and other medications that the individual is taking." *Id.* In light of the evidence of the risks and variations in individuals' responses to Coumadin, and the Surveyor's testimony as to the applicable professional standards of quality care for monitoring residents on Coumadin, the ALJ concluded that a SNF must "have a system in place to ensure that . . . : (1) INRs are performed as prescribed, and their results are reported timely to the residents' physicians; and (2) those residents who receive Coumadin have care plans that address the drug's risks to these residents." *Id.*

Contrary to Universal's contention, the ALJ did not err in relying on the Surveyor's testimony to ascertain the professional standards of quality care to ensure that residents administered Coumadin are "free from unnecessary drugs" and with "adequate monitoring" within the meaning of section 483.25(l). As the Board previously has held, "the quality of care regulation implicitly imposes" on SNFs the "duty to provide care and services that, at a minimum, meet accepted professional standards of quality 'since the regulations elsewhere require that the services provided or arranged by the facility must meet such standards.'" *Greenbrier Nursing and Rehabilitation Center*, DAB No. 2335, at 5 (2010), *citing Sheridan Health Care Center*, DAB No. 2178, at 15 (2008), quoting *Spring Meadows Health Care Center*, DAB No. 1966, at 17 (2005); *see also Omni*

Manor Nursing Home, DAB No. 1920 (2004) (holding that an accepted standard of clinical practice need not be specified in a regulation before it may be considered by an ALJ in assessing whether the skilled nursing facility was compliant). Further, an ALJ may rely on a surveyor's expertise as to applicable standards of professional care where the evidence shows that the surveyor has training, experience and knowledge in the subject field. *See, e.g.*, *Embassy Health Care*, DAB No. 2327, at 7-8 (2010); *The Residence at Salem Woods*, DAB No. 2052, at 7-8 (2006).

In this case, the Surveyor was a registered pharmacist with a Bachelor of Science degree in pharmacy, approximately 25 years of experience as a nursing home pharmacy consultant who "provided extensive consultation related to the use of the drug Coumadin," and five years of experience as a surveyor for the State agency. CMS Ex. 10, ¶¶ 1, 2.[2] In light of these qualifications, we conclude that the ALJ properly relied on the surveyor's opinion of the applicable standards of nursing care for monitoring residents on Coumadin therapy. The Surveyor's opinion, moreover, is substantiated by the "Coumadin Manufacturer's Specifications" at CMS Exhibit 2. The specifications warn of the "serious risk" of "[f]atal or nonfatal hemorrhage from any tissue or organ" posed by Coumadin therapy. *Id.* at 6, 12. In addition, the specifications state that "[i]t cannot be emphasized too strongly that *treatment of each patient is a highly individualized matter*" and that "[d]osage should be controlled by periodic [PT/INR] determinations." *Id.* at 6 (emphasis added). The specifications also identify "the elderly or debilitated" as "special risk patients" for whom "caution should be observed" when administering the drug because of the "added risk of hemorrhage." *Id.* at 11. Furthermore, the dosage and administration guidelines explain that dosage must be "adjusted based upon the patient's PT/INR" and that *a patient's "PT should be determined daily after the administration of the initial dose until PT/INR results stabilize in the therapeutic rang*e." *Id.* at 13-14 (emphasis added). The Coumadin manufacturer's warnings and guidelines thus amply support the ALJ's determination that a SNF must have systems in place to ensure that Coumadin PT/INR tests are performed as ordered, and that individualized patient care plans address the risks posed to each resident prescribed Coumadin.

The ALJ correctly construed and applied section 483.75(j)(1).

We additionally conclude that the ALJ properly rejected Universal's contention that section 483.75(j)(1) applies only to services performed by a laboratory and not SNFs such as Universal. The participation requirements for long term care facilities, including SNFs, are set forth in 42 C.F.R. Part 483, subpart B. Section 483.75(j)(1) provides that

[2] Universal argues that CMS did not tender the Surveyor's testimony as expert testimony and did not provide documentation to qualify the Surveyor as an expert. P. Br. at 21 n.4. It appears that Universal's contentions are based on the Federal Rules of Evidence, which do not apply to proceedings under 42 C.F.R. Part 498. 42 C.F.R. § 498.61. In any case, the record contains evidence establishing the surveyor's credentials and experience sufficient to support her expertise in the relevant field.

"*[t]he facility must provide or obtain* laboratory services to meet the needs of its residents" and "*[t]he facility is responsible* for the quality and timeliness of the services." (Emphasis added.) In addition, section 483.75(j)(2) makes clear that it is the "*facility*" that "must . . . [p]rovide or obtain laboratory services . . . when ordered by the attending physician," and "[p]romptly notify the attending physician of the findings." (Emphasis added.) Thus, the context and plain language of section 483.75(j) establish that the regulation's requirements apply to SNFs.

Furthermore, neither the ALJ Decision in *Woodland Village* nor Dr. Simonson's testimony, cited by Universal to support its argument that section 483.75(j) applies only to laboratories, provides a basis for ignoring the plain language of the regulation. The ALJ in *Woodland* determined that CMS had failed to demonstrate a prima facie case of noncompliance with section 483.75(j) where a facility had failed to perform a physician-ordered test. DAB CR1668, at 33. This issue, however, was not appealed and, consequently, not addressed by the Board. *See* DAB No. 2172 (2008). ALJ decisions, moreover, are not precedential but are relevant to a Board analysis "only for the inherent value of any persuasive analysis therein." *Singing River Rehabilitation and Nursing Center*, DAB No. 2232, at 11 n.7 (2009). Dr. Simonson's testimony that section 483.75(j) "addresses services performed by the laboratory rather than the nursing facility" is purely a legal conclusion (as distinguished from expert medical testimony that, for example, evaluates a resident's medical condition, explains professionally accepted standards of care, or assesses the adequacy of the services provided) that the ALJ properly rejected. P. Ex. 23, ¶ 3; *Dumas Nursing and Rehabilitation*, L.P., DAB No. 2347, at 19 (2010) ("an administrative law judge is not bound by a witness's legal conclusions"), *citing Guardian Health Care Center*, DAB No. 1943, at 11 (2004).

The ALJ properly relied on the factual findings in the SOD as evidence of Universal's noncompliance.

We further conclude that the ALJ properly relied on the factual findings in the SOD, as well as the Surveyor's testimony and R1's physician's orders, as evidence of Universal's noncompliance with the regulatory requirements. An SOD, the Board has held, "is a contemporaneous record of the survey agency's observations and investigative findings, and . . . CMS may make a prima facie showing of noncompliance based on that document if the factual findings and allegations it contains are specific, undisputed, and not inherently unreliable." *See Guardian Health Care Center* at 14, *citing Glenburn Home*, DAB No. 1806, at 25 (2002). In this case, Universal does not dispute the specific factual findings in the SOD, cited by the ALJ, that during the February 10 through March 24, 2009 period, R1's response to Coumadin was unstable, at times critically high, and at other times subtherapeutic; that five physician-ordered PT/INR tests for R1 were not performed or obtained to monitor R1; that there was no specific provision in R1's care plan addressing the Coumadin therapy, its potential side effects, or the need for staff to take special precautions with R1 to prevent bleeding; or that the clinical impression noted

in the March 24, 2009 hospital emergency room report was "respiratory arrest, upper gastrointestinal bleeding and Coumadin toxicity."[3] CMS Ex. 1, at 3, 6-16, 20-25. Indeed, Universal admits that "on March 21, 2009, a PT/INR was due but not drawn," and "acknowledges that four missed labs occurred prior to the March 21, 2009, missed lab. . . ." P. Br. at 5, 9. These findings in the SOD, moreover, are substantiated by additional record evidence, including R1's physician orders (also cited by the ALJ), nurse's notes, physician progress notes, medication administration records, Meridian Laboratory reports, R1's care plan, and hospital records. ALJ Decision at 4-5; P. Exs. 2-6, 14; CMS Exs. 4, 5, 7.

Although it does not dispute this evidence, Universal does contend that the SOD "erroneously alleges" that it "failed to notify [R1's] physician of PT/INR results from [the] February 24 and March 3, 2009 lab draws respectively." P. Br. at 6, n.3, *citing* CMS Ex. 1, at 8, 10. The ALJ Decision, Universal argues, "erroneously alleges the same fact regarding the February 24, 2009 PT/INR value." *Id.* Universal cites documentation that, it alleges, shows that the "February 24 lab result was received by the facility on February 26 and called in to the physician," and that the "March 3 lab was received by the facility on March 5 and called in to the physician, who signed the lab result the next day on March 6, 2009." *Id. citing* P. Ex. 3, at 9, 11 (nurse's notes); P. Ex. 5, at 5, 8 (laboratory reports). We reject these allegations of error for the reasons discussed below.

Universal's argument that the SOD erred by stating, and the ALJ by finding, that there was no evidence that the facility notified R1's physician of the results of a February 24 lab draw or February 24 lab results assumes there was a draw or results on February 24. As support, Universal cites a nurse's note indicating that the facility received "critical PT/INR results" from the laboratory on February 26 and notified R1's physician of those results. P. Br. at 6, n.3, citing CMS Ex. 1, at 8. While this note is evidence that Universal staff notified R1's physician of lab results it received on February 26, 2009, it is not evidence that the lab results reported were for a February 24 blood draw because the note does not identify the date of the draw for the results reported.

Universal also cites a laboratory report that shows a "draw date" of February 24, 2010. P. Br. at 6, n.3, *citing* P. Ex. 5, at 5. This laboratory report appears to be the source of the statement on the SOD, "Record review of the laboratory draw for 02/24/09 reported at 2:04 PM revealed a significantly elevated PT of 89.6 (normal 9.9-12.2 and INR of 7.27 (normal 2-3)." CMS Ex. 1, at 7-8. The SOD further states that in "*the physician's progress notes for 02/25/09*" there was "no indication . . . that the physician was aware of the elevated PT/INR of 02/24/09." *Id.* at 8 (emphasis added). The ALJ refers to the SOD

[3] Universal's expert witness testified that "when the resident declined and expired, the hospital had not taken all measures which were available to bring down [R1's] INR and that her family withheld further care." P. Br. at 8, *citing* P. Ex. 24, ¶ 14. This testimony addresses what actions the hospital took to address the resident's condition *after* emergency room staff assessed her condition and, thus, this testimony is not inconsistent with the clinical impression.

in his reference to the "February 24, 2009 . . . INR result" for which he found no evidence showing that the results were reported to R1's physician. ALJ Decision at 4, *citing* CMS Ex. 1, at 7-8.

However, the record indicates that, contrary to what Universal asserts (and what the ALJ may have assumed), i.e., that the blood draw ordered for February 24 actually occurred on February 24, the draw was not actually done until February 26. The same laboratory report discussed above shows a "delivery date" of February 26, 2009, at 12:53 p.m. and "results approved" at 2:04 p.m. on February 26. This suggests that either the blood was drawn two days before it was delivered to the lab or that the blood was not actually drawn until as late as the morning of February 26, 2009. The SOD later clarifies that no draw or lab report of an elevated PT/INR result actually occurred until February 26. According to the SOD, a laboratory supervisor told the surveyors that it was "the *order* for a blood draw [that] was put in the computer on 02/24/09 at 6:25 AM." CMS Ex. 1, at 8 (emphasis added). The supervisor also told the surveyors that the phlebotomist was unaware of that order when she was in the facility earlier on the morning of February 24, and a Universal nurse reported that the sample was not actually drawn until February 26, 2009. *Id.* at 8-9. Consistent with this statement, the nurse's notes for February 24, 2009 do not indicate blood was drawn. Moreover, a notation above the record copy of the physician's telephone order of February 26, 2009 reads, "missed draw on 2/24/09 done 2/26/09." CMS Ex. 7, at 5.

Accordingly, the only "error" in the ALJ's statement, "There is no evidence that the physician was notified of [the February 24] reading," is the underlying assumption that a lab draw and reading actually occurred on February 24. ALJ Decision at 4. Because, the evidence shows, neither a draw nor lab testing (or results) occurred on that date, the more precise statement would be that the evidence indicates that the physician's order for a February 24 draw was not followed. Moreover, the ALJ went on to state, "However, on February 26, 2009, the physician – evidently after having been notified about another very high INR result – ordered for a second time that administration of Coumadin and Lovenox be discontinued." *Id*. *citing* CMS Ex. 7, at 5 (February 26, 2009) physician phone order). Thus, contrary to what Universal suggests, the ALJ found that the physician was notified of *a* lab result on February 26.

We need not address Universal's allegation that the SOD erroneously stated that there was no documentation to confirm that the physician was notified of a March 3 lab report because the ALJ, as Universal does not dispute, did not make a finding based on the alleged error. An ALJ's review of the factual and legal bases underlying a CMS determination of facility noncompliance is a "de novo" proceeding. *SunBridge Care and Rehabilitation for Pembroke*, DAB No. 2170, 26-27 (2008), *aff'd, Sunbridge Care and Rehabilitation for Pembroke v. Leavitt*, 340 F. App'x 929 (4th Cir. 2009). Since the ALJ did not find that there was no documentation to confirm that the physician was notified of a March 3 lab report, we need not address Universal's argument. The ALJ did find that

on "March 2, 4, and 5, the resident's INR readings were subtherapeutic" and that Universal's "staff did not notify [R1's] physician of *these* abnormal results until March 5, 2009." ALJ Decision at 4 (emphasis added). Universal does not dispute this ALJ finding, which indicates that even when abnormal results were reported to R1's physician, the reports were not always timely.

> *The ALJ did not err in determining that Universal's failure to address the Coumadin therapy in R1's care plan constituted noncompliance with section 483.25(l).*

We also reject Universal's argument that the ALJ erred in citing care planning deficiencies as a basis for finding the facility noncompliant with section 483.25(l). Contrary to Universal's contention, the SOD does explicitly identify Universal's failure to address the Coumadin therapy in R1's care plan as one of the numerous deficiency findings listed under section 483.25(l) which, in combination, posed immediate jeopardy to resident health or safety. Specifically, the SOD includes under the quality of care, unnecessary drugs, citation the statement that the "updated care plan for Resident #1 revealed no documentation about the Coumadin and its potential side effects or [the] need for bleeding precautions." CMS Ex. 1, at 10.

Furthermore, the ALJ did not err in evaluating the sufficiency of R1's comprehensive care plan in the context of the section 483.25(l), quality of care requirements. While the regulations at 42 C.F.R. §§ 483.20 ("Resident assessment") and 483.20(k) ("Comprehensive care plans") "deal[] more specifically with assessments and the development of care plans," the Board has held that the quality of care provisions "effectively incorporate[] those [care planning] requirements" through the introductory language of section 483.25. *Azalea Court*, DAB No. 2352, at 12 (2010). The introductory language states that the facility must provide each resident "the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, *in accordance with the comprehensive assessment and plan of care*." 42 C.F.R. § 483.25 (emphasis added). Such "care and services," the Board has held, include monitoring and adequately documenting the resident's condition and ensuring the sufficiency of care plans. *The Laurels at Forest Glenn*, DAB No. 2182, at 6 (2008). Moreover, the regulations do not prohibit CMS from citing care planning deficiencies simultaneously under sections 483.25(l), 483.20(d) and 483.20(k)(1). *See Brian Center Health and Rehabilitation/Goldsboro*, DAB No. 2336, at 6 (2010) (if a given set of facts demonstrates that a facility has violated more than one participation requirement, CMS may, in its discretion, charge the facility with violating any, or all, of the applicable requirements); *see also Oak Lawn Pavilion, Inc.*, DAB No. 1638, at 8-12 (1997) (facility not prejudiced by ALJ finding noncompliance with quality of care requirement based in part on facts cited under other unmet requirements because it had notice from SOD that CMS intended to rely on those facts as part of its proof of noncompliance).

In addition, while the regulations do not specifically address the need to monitor and develop interventions for Coumadin therapy in the comprehensive care plan of each resident taking the drug, the regulations and governing statutes require facilities to include all prescribed medications in each resident's comprehensive assessment and to develop and update each comprehensive care plan based on the medical and nursing needs identified in the assessment. 42 C.F.R. §§ 483.20(b), 483.20(k)(1); 42 U.S.C. §§ 1395i-3(b)(2)(A), 1395i-3(b)(2)(C), 1395i-3(b)(3)(A) . Consistent with these requirements, R1's care plan identified the need to monitor for therapeutic effectiveness and for adverse effects of the antianxiety drug, Klonopin, and the antidepressant, Doxepin. CMS Ex. 4. Yet, R1's care plan was not updated to document the need to monitor for therapeutic effectiveness and for adverse effects of the prescribed anticoagulants, or the need to take precautions in caring for R1 to prevent bleeding.

Universal's claim that CMS failed to introduce testimony or evidence of the professional standards on which it based the care planning deficiency also has no merit. As explained above, the ALJ's conclusion that a SNF must have a system in place to ensure that "residents who receive Coumadin have care plans that address the drug's risks to these residents" is supported by the Surveyor's testimony, as well as the Coumadin Manufacturer's Specifications. ALJ Decision at 3, 5; CMS Exs. 2, at 6; 10, at 1-2. Given R1's complex medical problems, including her documented labile response to the administered anticoagulants, her total dependence on staff for bed mobility, transfers, dressing and bathing, and her documented risk for falls, the Surveyor testified, one "would expect" R1's individualized care plan to have included "daily skin checks (to check for signs of bruising); careful observation for signs of bleeding from the gums or signs of bleeding in urine or stool, and specific instructions to staff to touch, handle, and assist the resident with extreme care." CMS Ex. 10, ¶¶ 27, 28; CMS Ex. 1, at 6. Consistent with the Surveyor's testimony, the Coumadin Manufacturer's Specifications state that a patient's physician should be notified immediately of any unusual bleeding or symptoms of bleeding, including "prolonged bleeding from cuts . . . bleeding of gums from brushing, unusual bleeding or bruising, red or dark brown urine, red or tar black stools, headache, dizziness, or weakness." CMS Ex. 2, at 12. The specifications addressing Coumadin "overdosage" further provide that the "appearance of blood in stools or urine, . . . excessive bruising or persistent oozing from superficial injuries . . . are early manifestations of anticoagulation beyond a safe and satisfactory level." *Id.*

The Surveyor's testimony that R1's care plan should have included monitoring for signs and symptoms of adverse reaction to, or overdose of, Coumadin also is consistent with the Board's decision in *Greenbrier Nursing and Rehabilitation Center,* DAB No. 2335, at 10-11. In *Greenbrier,* the Board sustained the ALJ's determination that under section 483.25 the SNF "had a duty to anticipate and plan for [the] risk" of bleeding posed by the combination of Coumadin and antibiotics but failed to address this risk in the resident's care plan. *Id.*; s*ee also Life Care Center of Gwinnett*, DAB No. 2240, at 4 (2009)

("Because she was taking Coumadin, Resident['s] care plan called for gentle handling in transfers to avoid bumps and cuts."). R1's care plan, however, entirely failed to address the risks and care needs posed by the Coumadin therapy, including the need to monitor R1 consistently and comprehensively for signs and symptoms of adverse reactions or overdose, or to instruct staff to use special care when touching, assisting, or transferring R1. CMS Ex. 4.

We further reject Universal's contention that while R1's care plan did not specifically address the Coumadin therapy, Universal provided all of the Coumadin "monitoring services appropriate" for R1. P. Br. at 12-13, *citing Evergreen Nursing Care Center*, DAB No. 2069, at 34 (2007); P. Exs. 3, 22-26. As the ALJ observed, "the fact that there were five failures" to provide or obtain a physician-ordered PT/INR test "over a period of about a month, all undetected . . . is proof" that Universal failed to sufficiently monitor R1 for unnecessary drugs. ALJ Decision at 6. In addition, while some of the nurse's notes document the administration of Coumadin, draws for, and results of, PT/INR tests, and observations of bruising, the evidence does not establish that all direct care staff was following a consistent, comprehensive approach to monitoring R1 for the variety of signs and symptoms that could indicate an adverse reaction to, or overdose of, Coumadin, including monitoring for internal bleeding in urine or stool. [4]

Moreover, the evidence and testimony proffered by Universal also fail to show that direct care staff had been instructed to exercise any special care in assisting or transferring R1 because of the risk of internal bleeding posed by the Coumadin therapy. The evidence suggests that such instruction might have prevented the bruising and tenderness on R1's right side in the breast/armpit area that, together with the need to obtain a PT/INR blood draw on March 24, 2009, was the documented reason for R1's transfer to the hospital emergency room. P. Ex. 1, at 1. According to the Nurse's Notes and Resident Incident Report, Universal's Director of Nursing (DON) was told that a mechanical lift had been used to assist R1 in showering the day before, and Universal's physician witness testified that it was the "normal use" of the mechanical lift that "probably" caused the injury. CMS Ex. 8, at 2-3; P. Exs. 1, at 1; 3, at 16; 24, ¶ 13.

[4] R1's comprehensive care plan called for weekly skin assessments to monitor for pressure ulcers, not bruising that would indicate an adverse reaction to Coumadin. CMS Ex. 4, at 1.

Accordingly, we conclude that the ALJ correctly determined that Universal failed to comply substantially with the requirements of 42 C.F.R. §§ 483.25(l) and 483.75(j)(1).

B. The ALJ did not err in sustaining CMS's determination that Universal's noncompliance posed immediate jeopardy to resident health and safety from March 21, 2009 through September 27, 2009.

Universal's arguments

Universal argues that it "properly self-identified and corrected a problem with its laboratory system for obtaining, recording and following up on lab results for a single resident during a period between two annual surveys such that it should not have been cited" for immediate jeopardy noncompliance "at all." P. Br. at 1; *see also* P. Reply at 1-2. Specifically, Universal contends, under SOM section 7510A (2009), CMS should not have cited the facility for "past noncompliance" requiring the imposition of a CMP because uncontested evidence shows that "the alleged noncompliance occurred and was corrected between two periods of compliance," it had a quality assurance process in place that led to the implementation of corrective measures, and the noncompliance was not "egregious." P. Br. at 7-8; P. Ex. 13, at 9-10. Alternatively, Universal argues that "to the extent" it failed to comply substantially with sections 483.25(l) and 483.75(j)(1), CMS "should have found that any noncompliance at the immediate jeopardy level" lasted only until April 7, 2009, when it "self-identified the missed labs and . . . implemented appropriate and effective corrective measures" that "cured the deficiency." P. Br. at 1, 9, 16-22; P. Reply at 1-4.[5]

In support of these arguments Universal points to the testimony of its experts and staff, as well as facility documentation, as evidence that it "immediately implemented a number of steps" to remedy its "lab collection and reporting system" after a nurse discovered, on March 23, 2009, the missed March 21, 2009 PT/INR test. P. Br. at 17, *citing* P. Exs. 8-12, 14-15, 19-22. According to Universal, its self-initiated corrective measures were sufficient to correct any noncompliance but were "never considered" by the State agency. P. Reply at 2. Universal also argues that the ALJ erred in rejecting its unchallenged experts' testimony that these actions sufficiently addressed the facility's noncompliance and that "the absence of any missed labs after at least April 7, 2009, evidences the

[5] Universal's brief addresses at length the ALJ's reliance on *Omni Manor Nursing Home*, CR2213 (2010), as authority for his statement that, "[a]s a matter of law, CMS . . . could have determined the date of correction as late as the October Survey completion date of October 15. The deficiencies that are at issue in this case are . . . of the type that require surveyor observation of staff performance before compliance can be certified." P. Br. at 25-35; ALJ Decision at 10-11. We note that the Board reversed the ALJ Decision in *Omni Manor*, and remanded that matter for further findings in March 2011. DAB No. 2374 (2011). The Board concluded, among other things, that section 488.454(e) allows a provider appealing noncompliance findings that resulted in the imposition of a remedy the opportunity to attempt to establish a compliance date earlier than that determined by CMS or the state. Our analysis here is consistent with the Board's holding in *Omni Manor*. As we explain in detail above, Universal failed to establish that it returned to substantial compliance earlier than the date determined by CMS.

effectiveness of [Universal's] corrective actions." P. Br. at 20. Furthermore, Universal avers, the Surveyor's testimony was "devoid of any reference" to the corrective measures implemented by the facility, and CMS "presented no evidence to challenge [Universal's] abundant evidence" that the remedial measures abated any noncompliance. P. Br. At 21-23; P. Reply at 2. Universal also contends that the "post-survey additional measures" included in the plan of correction (POC) and implemented by September 27, 2009 were "essentially dictate[d]" by the surveyors and "were superfluous." P. Reply at 3; P. Br. at 23, 25.

The applicable standard of review

The regulations require that "CMS's determination as to the level of noncompliance of an SNF or NF (nursing facility) must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c). Under that standard, CMS's determination of immediate jeopardy here is presumed to be correct, and Universal has a heavy burden to demonstrate clear error in that determination. *See Brian Center Health and Rehabilitation/Goldsboro* at 9, *citing Barbourville Nursing Home*, DAB No. 1962, at 11 (2005), *aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Servs.*, 174 F. App'x 932 (6th Cir. 2006). Once CMS presents evidence supporting a finding of noncompliance, CMS does not need to offer evidence to support its determination that the noncompliance constitutes immediate jeopardy; rather, the burden is on the facility to show that that determination is clearly erroneous. *Liberty Commons Nursing & Rehab Center – Johnston*, DAB No. 2031 (2006), *aff'd, Liberty Commons Nursing & Rehab Ctr.— Johnston v. Leavitt*, 241 F. App'x. 76, at **3–**4 (4th Cir. 2007).

A "facility's burden extends to overcoming CMS's determination as to how long the noncompliance remained at the immediate jeopardy level." *Azalea Court*, DAB No. 2352 at 17, *citing Brian Center*, DAB No. 2336, at 7. In *Brian Center*, the Board held, CMS's judgment that a facility's corrective measures were insufficient to abate the immediate jeopardy prior to the date CMS determined "is, in essence, a determination that the *level* of noncompliance continued to present immediate jeopardy" to residents. DAB No. 2336, at 7 (emphasis in original). Thus, "[a] determination by CMS that a SNF's ongoing compliance remains at the level of immediate jeopardy during a given period constitutes a determination about the 'level of noncompliance' and, therefore, is subject to the clearly erroneous standard of review under section 498.60(c)(2)." *Id.* at 7-8.

Universal failed to demonstrate that CMS's determination that Universal's noncompliance posed immediate jeopardy was clearly erroneous.

We concur in the ALJ's conclusion that Universal did not demonstrate that the determination of immediate jeopardy made at the September survey was clearly erroneous. As discussed, substantial evidence supports the ALJ's findings that Coumadin

can cause life-threatening bleeding if not closely and carefully monitored, that a SNF must have systems in place to ensure that Coumadin PT/INR tests are performed as ordered and that individualized patient care plans address the risks posed to each resident prescribed Coumadin. The evidence further supports the ALJ's finding that R1's response to Coumadin remained unstable throughout March 2009. In light of the risks posed by the drug and R1's condition, Universal's failure to address the Coumadin in R1's comprehensive care plan, failure to comprehensively monitor R1 for adverse reactions to, or overdose of, Coumadin, and failure to timely obtain and timely report the results of multiple physician-ordered PT/INR tests together created a situation that was "likely to cause, serious injury, harm, impairment or death." 42 C.F.R. § 488.301. Accordingly, we agree with the ALJ that even if Universal's "failure to monitor effectively" R1's Coumadin "did not directly cause her death," it posed immediate jeopardy to her health and safety. ALJ Decision at 6.

Furthermore, Universal's contention that its deficiencies constituted the type of "past occurrence" for which a CMP should not have been imposed pursuant to section 7510A of the SOM is based on a flawed reading of the manual provision and a mischaracterization of the seriousness of its noncompliance. The version of section 7510A in effect during the applicable period provided that "past noncompliance" means "noncompliance that occurred between two certifications of compliance, against which a [CMP] is imposed." P. Ex. 13, at 9.[6] It further stated that "[i]f past noncompliance is cited, a [CMP] must be imposed." *Id.* The SOM also provided, however, that CMS and the State agency should not "cite" a facility for a "past occurrence" where: "(1) a facility has been out of compliance with a regulatory requirement between two surveys that found it in compliance, **and** (2) the noncompliance is not of the serious nature described [that includes immediate jeopardy], **and** (3) the facility has a quality assurance program in place and has corrected the noncompliance." *Id.* (emphasis in original). Here, contrary to Universal's argument, the deficiencies simply do not meet the three criteria for CMS not to cite the facility for past noncompliance for which a CMP should be imposed. As noted, neither the September 2009 complaint investigation survey nor the October 2009 revisit survey certified Universal to be in compliance. Moreover, the facility's noncompliance with sections 483.25(l) and 483.75(j)(1), detailed at length above, was of an extremely serious nature. In any event, the Social Security Act expressly authorizes, and the regulations provide for, the imposition of CMPs for immediate jeopardy noncompliance of "a previous period" even if, at the time of the survey, the facility is in substantial compliance. 42 U.S.C. 1395i–3(h); 42 C.F.R. § 488.430(b). *See also* 59 Fed. Reg. 56,116, 56,199 (Nov. 10, 1994) (explaining that the regulation implements the statutory provision, which permits a CMP to be imposed "whenever there is past noncompliance with the participation requirements between standard surveys"). The statute and regulations take precedence over manual provisions, which are not law.

[6] Section 7510 was revised under Rev. 63, issued and effective September 10, 2010.

We also agree with the ALJ that Universal did not prove CMS's determination that the immediate jeopardy persisted from March 21, 2009 through September 27, 2009 to be clearly erroneous. Universal's arguments, testimony, and evidence show that Universal understood, and continues to perceive, the nature of its noncompliance as a matter limited to "laboratory system" failures relating to a single resident. For example, Universal argues that "[t]his appeal primarily centers on whether [it] properly self-identified and corrected a problem with its laboratory system for obtaining, recording and following up on lab results for a single resident . . . ." P. Br. at 1; P. Reply at 1. Similarly, Universal's expert witnesses' declarations address "whether the facility's lab monitoring protocol as [of] April 7, 2009, was adequate and consistent with the standard of care." P. Ex. 23, ¶ 4; P. Ex. 24, ¶ 2. Likewise, Universal relies on the testimony of facility witnesses, written policies, and documentation of its corrective actions to show that it "implemented a number of steps to investigate and correct [the] error" that led to the "missed PT/INR lab draw of March 21, 2009" and "to ensure that all staff consistently followed" the facility's "lab collection and reporting" procedures. P. Br. at 16-17, *citing* P. Exs. 8-12, 14-15, 19-22. Those steps, as described by Universal, included:

- An investigation of the cause of the failure to obtain the physician-ordered March 21, 2009 PT/INR.

- "[I]mmediate bedside re-inservicing of direct care staff" on existing laboratory procedures.

- An evaluation of existing laboratory procedures, concluding that "they were appropriate and sufficient.

- Development of a new "Anticoagulate Therapy" form "for use by staff to monitor the PT/INR due dates and results for residents on Coumadin therapy."

- "Formal inservicing . . . of all pertinent direct care, management, and administrative staff on the existing laboratory protocol and procedures," and on the new form, completed by April 7, 2009.

- Implementation as of April 7, 2009, of an "ongoing monitoring process to oversee the effectiveness of the laboratory protocol."

P. Br. at 16-18; *see also* ALJ Decision at 7-8, *citing* Petitioner's Pre-Hearing Brief at 6-8.

The deficiencies that together posed a likelihood of serious injury or harm to R1 and other residents taking anticoagulant drugs were not, however, limited to problems with the facility's laboratory systems and procedures. Rather, as discussed at length above and accurately described by the ALJ, the "totality" of Universal's noncompliance also

involved insufficient care planning to address the risks posed by the administration of anticoagulants, lack of comprehensive monitoring for adverse drug reactions or overdoses, a failure to instruct staff to touch, handle and assist residents on anticoagulants with special care, and the failure of administrative staff to detect "the errors that rank and file care givers were committing in providing care . . . ." ALJ Decision at 8. Because Universal's self-implemented corrections failed to address these other aspects of the facility's noncompliance, the State agency and CMS reasonably determined that the immediate jeopardy continued beyond April 7, 2009. Moreover, because Universal's noncompliance involved more than failures to provide physician-ordered laboratory tests, the "absence of any missed labs after at least April 7, 2009" does not alone evidence that Universal's self-initiated corrective actions effectively abated the immediate jeopardy. P. Br. at 20.

We further find that the record evidence belies Universal's contention that its self-implemented corrections were never considered by the surveyors in their evaluation of when the facility abated the immediate jeopardy and returned to substantial compliance. The September survey SOD includes summaries of multiple surveyor interviews of facility staff and administrators (including nurses, the Unit Clerk, the Assistant DON, the former DON (employed during the February through early April 2009 period), and the DON at the time of the September survey) during which the facility's laboratory protocols and procedures were discussed. CMS Ex. 1, at 5-6, 8-10, 15-18, 20-22, 25-30; P. Exs. 11, 12. The summaries of those interviews also show that staff and administrators explained to the surveyors and provided documentation of the corrective measures initiated by the facility prior to the survey, including inservicing of nurses in March and April 2009, and the implementation of the April 2009 revised "anticoagulant therapy monitoring form" and "anticoagulate protocol." *Id.* Furthermore, according to Universal's Administrator and the Regional Clinical Director for Choice Health Management, on September 26, 2009, the facility submitted to the State agency a proposed credible allegation of compliance (CAC) "that referenced and explained the existing facility lab policies and procedures on which [Universal] had previously re-inserviced all staff by April 7, 2009, and the anticoagulant monitoring form" implemented by April 7. P. Ex. 19, at ¶ 7; P. Ex. 20, at ¶ 6 and Ex. A. The surveyors, the Administrator and Regional Clinical Director testified, did not accept the proposed CAC, and "insisted that the CAC be revised to include more monitoring steps." P. Ex. 19, at ¶ 8; P. Ex. 20 at ¶ 7.

We also note that even with respect to the corrective actions related to the laboratory protocols and procedures there is evidence contradicting the facility's claims of an earlier abatement date. The SOD shows that on September 26, the surveyors interviewed Universal's "consultant pharmacist," who "stated that she had some problems with laboratory evaluations," and that it "was often difficult to collate the information on her monthly review dates." CMS Ex. 1, at 16-17. The pharmacist also stated that "she had voiced her concerns to the facility nursing administration and they had instituted a lab

book but the book had fallen into disuse." *Id.* In addition, a February 2009 "Consultant Pharmacist Report" stated that the pharmacist "recommended [that staff] document any monitoring of the resident especially with a high INR (Over 3) [for] . . . bruising or bleeding." *Id.* at 17. "This type of monitoring," the pharmacist reported, "is not documented in the nursing notes when INRs are >3." *Id.* Thus, the evidence shows that the surveyors were aware of the measures taken by Universal as of April 7, 2009 to abate the immediate jeopardy and correct its noncompliance, but plainly found those measures insufficient.

Furthermore, the additional corrective actions identified in the approved plan of correction that were not fully implemented until September 28, 2009 – even if included at the insistence of the State agency as Universal asserts – provide evidence that concerns central to the reasons immediate jeopardy was found were not fully addressed. The additional corrective measures included:

- Universal's DON audited each resident care plan to identify residents receiving anticoagulants as of September 24, 2009, a follow-up review was completed by a licensed nurse, and care plans were revised to include signs and/or symptoms of bleeding.

- A temporary model care plan for residents on Coumadin was developed, and on September 25, 2009, copies of it were placed at the nurses' station and in the record of each resident who received Coumadin. The DON inserviced the licensed nurses on the temporary care plan on September 25, and the Minimum Data Set Assessment Coordinator was inserviced on procedures for updating care plans.

- The DON, Assistant DON, and Unit Manager were assigned the responsibility of auditing the medical records of the next 20 residents admitted to the facility who were receiving Coumadin for the presence of Coumadin care plans, and the results of those audits were to be reviewed at quality assurance meetings monthly for four months, and quarterly thereafter.

- A revised anticoagulant therapy form was implemented on September 24, 2009, to be filled out for each resident receiving Coumadin, Lovenox, or Heparin. The form, as filled out for each resident, would list the specific dose of anticoagulant medication that the resident was receiving, and would identify the next date when a PT/INR or similar test was to be performed. The filled-out forms would be kept in a binder at the nurses' station and no longer placed on the Medication Administration Record, pursuant to the facility's prior procedures.

- Any new resident on anticoagulants would have an anticoagulant therapy flow sheet initiated and an interim anticoagulant care plan placed in the medical record on admission.

- On September 24 and 25, 2009, staff was inserviced on the use of the new anticoagulant therapy form.

- On September 26, 2009, the pharmacy provided a roster of residents on Digoxin, Synthroid, Dilantin and Coumadin. The roster would be updated by the DON or Assistant DON with each morning clinical meeting with any newly ordered or discontinued medication requiring monitoring.

- On September 28, 2009, staff was inserviced on "stat" laboratory tests (tests that are ordered for an immediate response) and on laboratory tests that are sent to other designated facilities.

- The DON and Assistant DON were assigned the responsibilities of auditing the anticoagulant therapy forms daily and counseling each nurse who failed to follow facility protocol.

CMS Ex. 1, at 1-2, 8-9, 23-25. These actions, implemented at the end of September 2009, specifically responded to the care planning, comprehensive monitoring for adverse effects of anticoagulants, and administrative oversight deficiencies not previously addressed by Universal's self-initiated corrective measures. Accordingly, we concur in the ALJ's determination that Universal did not abate the immediate jeopardy until it developed and implemented the additional measures in its approved plan of correction in response to the September 2009 survey findings. Consequently, we conclude that CMS's determination that Universal did not abate its immediate jeopardy level noncompliance until September 27, 2009 was not clearly erroneous.

Finally, Universal mistakenly argues that "the ALJ apparently rejected or ignored . . . without any basis," its experts' unrebutted testimony that Universal's "lab systems and Coumadin monitoring system as of April 7, 2009" were sufficient and that "the additional procedures required by the State Agency surveyors . . . were superfluous and not necessary for compliance with either [section 483.25(l) or 483.75(j)(1)] or the standard of care." P. Reply at 9. The ALJ specifically addressed the declarations of Universal's experts, explaining why he concluded that their testimony was not persuasive. Dr. Menscer, the ALJ observed, "offer[ed] no explanation why the [additional] corrective actions . . . . were superfluous," and her testimony focused on the failure to perform the PT/INR test ordered for R1 on March 21, 2009 "as if that failure was the *only* error committed by Petitioner and its staff . . . ." ALJ Decision at 9 (emphasis in original). The narrowness of that focus, the ALJ concluded, "undercuts her credibility." *Id.* at 10. The ALJ found Dr. Simonson's testimony unpersuasive because it, too, focused narrowly

on the March 21 failure to perform or obtain an INR test for R1. The ALJ found that while "[m]aking sure that the staff performed lab testing as ordered certainly addressed a problem," the corrections addressing that problem "did not address other problems, such as the failure of the staff to plan for the care of residents receiving anticoagulants or the failure of the staff to recognize that out of therapeutic range INR test results required physician consultation." *Id.* at 10. On review of the record, we conclude that the ALJ accurately described Universal's experts' testimony and provided a well-reasoned basis for why he found it unpersuasive.

Accordingly, we conclude that the ALJ correctly upheld CMS's determination that Universal's noncompliance with sections 483.25(l) and 483.75(j)(1) posed immediate jeopardy from March 21, 2009 through September 27, 2009.

C. The ALJ correctly concluded that CMS's CMP determinations were reasonable.

As noted, CMS imposed a CMP of $3,050 per day for each day of the March 21, 2009 through September 27, 2009 immediate-jeopardy period of noncompliance. CMS also imposed a CMP of $150 per day for each day of the September 28, 2009 through November 2, 2009 period. The ALJ assessed whether these amounts were reasonable applying, as required, the factors at 42 C.F.R. § 488.438(f)(1)-(4).

The ALJ concluded that the $3,050 per-day CMP that CMS imposed to address Universal's immediate jeopardy noncompliance was "reasonable as a matter of law." ALJ Decision at 11. The ALJ correctly noted that the minimum per-day amount that may be imposed to remedy noncompliance that poses immediate jeopardy is $3,050. 42 C.F.R. § 488.438(a)(1)(i). Universal disputed the ALJ's determination that the CMP of $3,050 per day imposed for the period March 21, 2009 through September 27, 2009 was reasonable only on the ground that "it rests upon a finding of continued noncompliance at the I[mmediate] J[eopardy] level" for that period. P. Br. at 36. Because we uphold the ALJ's determination that Universal "manifested immediate jeopardy level noncompliance throughout" the March 21, 2009 through September 27, 2009 period, we also uphold the $3,050 per-day CMP imposed for that period, which was reasonable as a matter of law under section 488.438.

On appeal, Universal does not dispute the CMP of $150 per day for the period September 28, 2009 through November 2, 2009. P. Br. at 36. Thus, we sustain the ALJ's conclusion that the penalty was reasonable without further discussion.

Conclusion

For the reasons stated above, we affirm the ALJ Decision.

_____/s/_____
Leslie A. Sussan

_____/s/_____
Constance B. Tobias

_____/s/_____
Sheila Ann Hegy
Presiding Board Member